STATE OF FLORIDA
DEPARTMENT OF HEALTH

BOARD:	Medicine
CASE NUMBER:	2005-67301
COMPLAINT MADE BY:	DOH/AHCA Infusion
COMPLAINT MADE AGAINST:	Claude Delmas, M.D. 385 N.E. 159th Street North Miami Beach, FL 33162
DATE OF COMPLAINT:	October 24, 2005
INVESTIGATED BY:	Robert Radin, MMI Miami ISU
ATTORNEY FOR RESPONDENT:	Pro Se
REVIEWED BY:	Diane K. Kiesling Assistant General Counsel
RECOMMENDATION:	Dismiss (4099)

NOTICE OF DISMISSAL/CLOSING ORDER
RECONSIDERATION

THE COMPLAINT: The Complainants, Department of Health (DOH) and Agency for Health Care Administration (AHCA) filed a complaint that Respondent had billed Medicare for treatments provided to Medicare beneficiaries at Novella Medical Center located at 1498 N.W. 54th Street, Miami, Florida. When a joint DOH/AHCA task force attempted inspection at that location, it was determined that the clinic had been closed for one to two months. It was alleged that the Medicare billing records showed that the Respondent billed for treatment to Medicare beneficiaries after the clinic closed.

THE FACTS: The facts are that an Administrative Complaint was filed on June 27, 2011, based on records that were provided by Medicare and not in response to Department subpoenas or patient releases. The Administrative Complaint contains allegations regarding 2 patients and it charges Respondent with violating the standard of care in numerous ways, with participating in a scheme to support fraudulent billing to Medicare for unnecessary or unreasonable care and services, with making or filing false reports which the license knew to be false, and with failing to maintain medical records

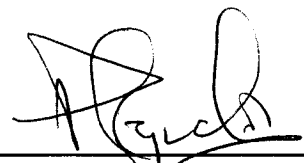
that justify the course of treatment. The Administrative Complaint is based on the expert opinion of a Department expert who reviewed the records that the Department received from Medicare, not from the clinic or the Respondent. Respondent had no access to the clinic records and was not the records owner. The records from Medicare (CMS) came in the form of a password protected disc. Medicare is no longer willing to cooperate in this investigation, and even if it was, it cannot provide a records custodian to authenticate the medical records. Of even greater concern is that the Department never issued a Reasonable Cause Subpoena for the medical records of these patients and it does not have a patient release to have these records in its possession. At this time, more than six years after the events in question, it will be impossible to prove these charges by clear and convincing evidence without patient records because the records cannot be authenticated, no subpoenas were served, and the allegations in the Administrative Complaint are not support by the evidence.

Therefore, sufficient evidence no longer exists to support the prosecution of the allegations contained in the Administrative Complaint and it should be dismissed.

THE LAW: There was sufficient evidence for the Panel to have found probable cause in this case. However, based on the above facts and analysis, the Department, pursuant to the provisions of Section 20.43(3), Florida Statutes, has determined that there is insufficient evidence to support the prosecution of the allegations contained in the Administrative Complaint. Therefore, pursuant to Section 456.073(2), Florida Statutes, this case is hereby DISMISSED.

It is, therefore, ORDERED that this case should be and the same is hereby DISMISSED.

DONE AND ORDERED this ____ day of _____, 2012.



Chairperson, Probable Cause Panel
Board of Medicine

DKK

PCP: February 24, 2012
PCP Meeting: Miguel, Nuss

DOH v. Claude Delmas, M.D., DOH Case No. 2005-67301

A-39 San Filippo

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2005-67301**

CLAUDE DELMAS, M.D.,

RESPONDENT.
_____/

ADMINISTRATIVE COMPLAINT

Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Medicine against Respondent, Claude Delmas, M.D., and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of medicine pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 458, Florida Statutes.

2. At all times material to this Complaint, Respondent was a licensed physician within the state of Florida, having been issued license number ME 51179.

3. Respondent's current address of record is 1980 Opa Locka Boulevard, Opa Locka, Florida 33054.

4. At all times material to this complaint, Respondent treated HIV/AIDS patients at Novella Medical Center, located at 1498 N.W. 54th Street, Miami, Florida 33142.

5. At all times material to this complaint Respondent was not Board Certified in any American Medical Board specialty.

GENERAL ALLEGATIONS

6. Human immunodeficiency virus (HIV) is a retrovirus. HIV integrates its RNA into the DNA of human cells and replicates, causing infection. As the virus replicates, it infects healthy cells, spreading the infection throughout the body. HIV easily spreads through billions of cells in the body if replication is not halted.

7. The primary treatment for HIV is antiretroviral treatment. This treatment consists of a combination of drugs that work against HIV by slowing the replication process. The drugs utilized in this HIV treatment are known by several generic terms: antiretroviral drugs, anti-HIV drugs, and/or HIV antiviral drugs.

8. For antiretroviral treatment to have long term efficacy, the treatment must consist of more than one antiretroviral drug. This treatment is known as "Combination Therapy." If the treatment consists of a combination of more than three antiretroviral drugs, it is called "Highly Active Antiretroviral Therapy ("HAART")."

9. In addition to treating HIV by slowing replication of the virus, there are several drugs currently used to address the symptoms of the disease, including symptoms produced as side effects of antiretroviral therapy. These drugs include immune globulin ("IVIG"), vitamin B12, Neupogen, and Procrit, sometimes administered as long-term intravenous infusions.

10. IVIG (Gamunex) is a preparation of antibodies collected from human blood donors. These antibodies (immune globulins) can be delivered into the body to help fight certain infections and to help treat some immune system diseases. It is also used to increase the blood count (platelets) in persons with a certain blood disorder (idiopathic thrombocytopenia purpura). IVIG is administered by slow infusion into a vein.

11. Peripheral neuropathy is the term for damage to the nerves of the peripheral nervous system, which may be caused either by diseases of the nerve or from the side-effects of systemic illness.

12. CD4 cells are a type of white blood cell that fights infection. A normal CD4 count is from 500 to 1,500 cells per cubic millimeter of blood.

13. Pneumocystis carinii pneumonia (PCP) is a fungus that can cause fatal pneumonia. PCP is a common presenting manifestation of the acquired immunodeficiency syndrome (AIDS) and is a major and recurring cause of morbidity and mortality for persons infected with the HIV.

14. Cytomegalovirus Immune Globulin Intravenous (Human) (Cytogam) is a medication used to prevent a certain serious viral infection (cytomegalovirus-CMV) in persons having an organ transplant. This medication is made from healthy human blood that has high levels of antibodies that help fight CMV. Cytogam is often used with the antiviral medication ganciclovir.

15. Sandostatin is the brand name for octreotide. Sandostatin Is used to treat severe watery diarrhea and sudden reddening of the face and neck caused by certain types of tumors (e.g., carcinoid tumors, vasoactive intestinal peptide tumors) that are found usually in the

intestines and pancreas. The symptoms occur when these tumors make too many hormones. This medication works by blocking the production of these hormones. By decreasing watery diarrhea, Sandostatin helps to reduce the loss of body fluids and minerals. Sandostatin is lso used to treat a certain condition (acromegaly) that occurs when the body makes too much growth hormone.

16. Medicare is a system of health insurance for the aged and disabled. The Department of Health and Human Services ("HHS"), through the Health Care Financing Administration ("HCFA"), administers the Medicare program. Medicare Part B covers the costs incurred by eligible beneficiaries for certain medical services. The Medicare program reimburses only care that is reasonable and necessary for the treatment or diagnosis of illness or injury. Medicare reimbursement is not permitted for unnecessary or unreasonable care and services.

17. At all times material hereto, Respondent provided intravenous treatments to Medicare patients that had been diagnosed with HIV. These treatments were billed to Medicare under Respondent's Medicare provider number.

18. On or about September 29, 2005, the Joint State and Federal Interagency Task Force Team (Team) attempted to conduct an inspection

at the Novella Medical Center (Novella), located at 1498 N.W. 54th Street, Miami, Florida 33142. Upon arrival, the Team discovered that Novella had been closed for up to 2 months. Medicare billing records show that Respondent continued to submit claims for infusion treatments allegedly provided to patients after Novella was closed. As of September 14, 2005, Respondent had billed Medicaid/Medicare $1.3 million dollars for infusion therapy, and had $1.8 million dollars in claims pending.

SPECIFIC ALLEGATIONS PERTAINING TO PATIENTS

Patient NB

19. From on or about June 23, 2005, until on or about September 22, 2005, Patient NB, a then 53 year-old male, presented to Respondent for HIV/AIDS treatment.

20. Respondent did not perform an adequate assessment of the patient's complaints and symptoms. Respondent did not accurately diagnose the patient's condition.

21. Respondent did not consult with any specialists, or refer the patient to any specialists, for an accurate diagnoses and proper treatment of the patient's complaints and medical condition.

22. Respondent submitted claims to Medicare for medical services ostensibly performed on June 23, 2005, June 25, 2005, July 5, 2005,

September 13, 2005, September 15, 2005, September 17, 2005, September 20, 2005, and September 22, 2005. Respondent's office (Novella) was closed on September 13, 2005, September 15, 2005, September 17, 2005, September 20, 2005, and September 22, 2005.

23. Respondent submitted statements to Medicare claiming that on June 23, 2005, June 25, 2005, and July 5, 2005, he prescribed "Neupogen 5 u sc qod x 4 wks" as part of the patient's treatment for HIV. Neupogen is supplied in single dose vials or single dose pre-filled syringes of the drug in micrograms (mcg), and is not supplied in units. Respondent did not follow the recommended dosing and, or follow the recognized standard of care. Respondent's medical records do not document the procedure being performed; the records do not contain an accurate diagnosis necessitating the administration of Neupogen as prescribed; and the records do not support the procedure billed by Respondent. Respondent did not document patient's body temperature reading.

24. Respondent submitted statements to Medicare claiming that on August 30, 2005, Respondent prescribed "Neupogen 5 mg three times per week for 4 weeks" for the patient as part of his treatment for HIV. It has only been in rare instances that patients with congenital neutropenia

have required doses of Neupogen ≥ 100 mcg/kg/day. Respondent did not order a current Absolute Neutrophil Count (ANC) laboratory study or the route of administration before prescribing Neupogen to the patient. An ANC laboratory report drawn on September 6, 2005, indicated a normal range of 2.7. Respondent did not follow the recommended dosing and, or follow the recognized standard of care. Respondent's medical records do not document the procedure being performed; the records do not contain an accurate diagnosis necessitating the administration of Neupogen as prescribed; and the records do not support the procedure billed by Respondent.

25. Respondent submitted statements to Medicare claiming that on June 23, 2005, June 25, 2005, July 5, 2005, September 13, 2005, September 15, 2005, September 17, 2005, September 20, 2005, and September 22, 2005, he prescribed 200 units of Epoetin Alfa therapy as part of the patient's treatment for HIV. Medicare will consider Epoetin Alfa therapy medically reasonable and necessary for anemia of chronic renal failure, anemia induced by AZT. To initiate Epoetin Alfa therapy, the patient **must** have a documented anemia as evidenced by symptoms and hematocrit (HCT) < 33% or a hemoglobin (HGB) < 11g/d unless there is medical documentation showing the need for Epoetin Alfa despite a HCT

> 32.9 or a HGB > 11g/d. The physician must clearly document in the medical record that all requirements have been met and support the medical necessity for the use of Epoetin Alfa, including, but not limited to covered diagnoses, appropriate laboratory studies (including date and results of most recent HCT/HGB levels within last month), dosage, route of administration, frequency and duration of the treatment and the patient's response to the therapy. Respondent's medical record did not contain any progress notes, any documentation that the procedure was actually performed on the billed date of service, any documentation of a HGB < 11g/d or a HCT < 33% within the last month, any documentation of a covered diagnosis, and any documentation of the patient's response. The medical record does not contain any laboratory reports applicable to the billed dates. Respondent did not accurately diagnose and, or document the patient with anemia. Respondent did not document any medical necessity for the use of Epoetin Alfa, including but not limited to covered diagnoses, appropriate laboratory studies, dosage, route of administration, frequency and duration of the treatment, and the patient's response to the therapy. Epoetin Alfa is supplied and billed per 1,000 units, according to Respondent's records he prescribed and, or administered 200,000 units for which he billed Medicare (200 x 1,000 =

200,000 units). Respondent did not follow the recommended dosing and, or follow the recognized standard of care.

26. Respondent submitted statements to Medicare claiming that on June 23, 2005, June 25, 2005, and July 5, 2005, he prescribed "Procrit 200u sc qod x 4 wks" as part of the patient's treatment for HIV. Procrit is indicated for the treatment of anemia in Zidovudine-treated HIV-infected patients. Procrit is supplied in single dose vials to multi-dose vials from 2,000 units/ml to 10,000 units/ml. It is recommended that Procrit be administered in units/kg, with doses ranging from 50 units/kg to 150 units/kg. Respondent did not follow the recommended dosing and, or follow the recognized standard of care. Respondent's medical records do not document the procedure being performed; the records do not contain an accurate diagnosis necessitating the administration of Procrit as prescribed; and the records do not support the procedure billed by Respondent.

27. Respondent submitted statements to Medicare claiming that on August 30, 2005, he prescribed "Procrit 200u sc weekly" as part of the patient's treatment for HIV. Respondent did not follow the recommended dosing and, or follow the recognized standard of care. Respondent's medical records do not document the procedure being performed; the

records do not contain an accurate diagnosis necessitating the administration of Procrit as prescribed; and the records do not support the procedure billed by Respondent.

28. Respondent submitted statements to Medicare claiming that on June 23, 2005, June 25, 2005, July 5, 2005, September 13, 2005, September 15, 2005, September 17, 2005, September 20, 2005, and September 22, 2005, he prescribed 480 mcg of Filgrastim (G-CSF) as part of the patient's treatment for HIV. Medicare will consider G-CSF medically reasonable and necessary for severe chronic neutropenia (SCN) patients to reduce the incidence and duration of sequelae of neutropenia, e.g., fever, infections, ulcers in symptomatic patients with SCN. Medicare will also consider G-CSF medically reasonable and necessary for off-label indication of amelioration of leucopenia in AIDS patients on AZT or AIDS patients with chorioretinitis on Ganciclovir. For Medicare to consider whether G-CSF is medically reasonable and necessary, medical record documentation maintained by the physician must clearly indicate the patient's current ANC; the patient's weight in kilograms; the administration and dosage of G-CSF; the actual indication for which the drug was given and accompanying symptomology (e.g., fever); and, the patient's response to the treatment. Respondent did not clearly document

the patient's current ANC count, the patient's current temperature reading, the frequency and duration of the treatment, and the patient's response to the therapy or any medical necessity for the use of G-CSF. Respondent did not follow the recommended dosing and, or follow the recognized standard of care. Respondent's medical records do not document the procedure being performed; the records do not contain an accurate diagnosis necessitating the administration of G-CSF as prescribed; and the records do not support the procedure billed by Respondent.

29. Respondent submitted statements to Medicare claiming that on June 23, 2005, June 25, 2005, and July 5, 2005, he prescribed 100 mg of Rituximab to the patient as part of his treatment for HIV. Respondent did not follow the recommended dosing and, or follow the recognized standard of care. Respondent's medical records do not document the procedure being performed; the records do not contain an accurate diagnosis necessitating the administration of Rituximab as prescribed; and the records do not support the procedure billed by Respondent.

30. Respondent submitted statements to Medicare claiming that on June 23, 2005, June 25, 2005, and July 5, 2005, he administered intravenous infusion-hydration (for up to one hour), as part of the

patient's treatment for HIV. Respondent did not follow the recommended dosing and, or follow the recognized standard of care. Respondent's medical records do not document the procedure being performed; the records do not contain an accurate diagnosis necessitating the administration of intravenous infusion-hydration as prescribed; and the records do not support the procedure billed by Respondent.

31. Respondent submitted statements to Medicare claiming that on June 23, 2005 and June 25, 2005, he administered intravenous infusion-hydration (for up to eight hours), as part of the patient's treatment for HIV. Respondent's medical records do not document the procedure being performed; the records do not contain an accurate diagnosis necessitating the administration of intravenous infusion-hydration as prescribed; and the records do not support the procedure billed by Respondent.

32. Respondent submitted statements to Medicare claiming that on June 23, 2005, June 25, 2005, and July 5, 2005, he administered an infusion of 1,000 cc normal saline solution as part of the patient's treatment for HIV. Respondent's medical records do not document the procedure being performed; the records do not contain an accurate diagnosis necessitating the administration of an infusion of 1,000 cc

normal saline solution as prescribed; and the records do not support the procedure billed by Respondent.

33. Respondent submitted statements to Medicare claiming that on June 23, 2005, June 25, 2005, July 5, 2005, September 13, 2005, September 15, 2005, September 17, 2005, and September 20, 2005, he introduced a needle or intra-catheter, as part of the patient's treatment for HIV. Respondent's medical records do not document the procedure being performed; the records do not contain an accurate diagnosis necessitating the introduction of a needle and, or intra-catheter as prescribed; and the records do not support the procedure billed by Respondent.

34. Respondent submitted statements to Medicare claiming that on September 13, 2005, September 15, 2005, September 17, 2005, September 20, 2005, and September 20, 2005, he administered imiglucerase as part of the patient's treatment for HIV. Imiglucerase is indicated for long term enzyme replacement therapy for adult patients with a confirmed diagnosis of Type I Gaucher disease. The medical records submitted by Respondent do not reflect the procedure being performed, any laboratory results, any documentation of the symptomology, and any diagnosis of Gaucher disease. Respondent's

medical records do not document the procedure being performed; the records do not contain an accurate diagnosis necessitating the administration of imiglucerase as prescribed; and the records do not support the procedure billed by Respondent.

35. Respondent submitted statements to Medicare claiming that on June 23, 2005, June 25, 2005, July 5, 2005, September 13, 2005, September 15, 2005, September 17, 2005, September 20, 2005, and September 22, 2005, he prescribed antiretroviral medications as part of the patient's treatment for HIV. The documentation submitted by respondent does not contain an order or prescription for the patient to receive antiretroviral medications.

36. Respondent did not accurately and completely document the patient's condition and treatment, and he did not pursue an appropriate plan of treatment for the patient.

37. Respondent's medical records do not justify the course of treatment utilized in the care of the patient, and his medical records do not support or justify the fees and costs for procedures billed.

38. Respondent submitted statements to Medicare claiming that he provided medical services for the patient on September 13, 2005,

September 15, 2005, September 17, 2005, September 20, 2005, and September 22, 2005. Respondent's office was closed on those dates.

Patient DA

39. From on or about June 7, 2005, until on or about September 22, 2005, Patient DA, a then 44 year-old male who was HIV positive with Hepatitis C, presented to Respondent for a physical evaluation.

40. Respondent did not perform an adequate assessment of the patient's complaints and symptoms. Respondent did not accurately diagnose the patient's condition.

41. Respondent submitted claims to Medicare for medical services ostensibly performed on June 7, 2005, June 9, 2005, July 7, 2005, July 12, 2005, July 19, 2005, August 20, 2005, August 23, 2005, August 25, 2011, September 6, 2005, September 10, 2005, September 13, 2005, September 15, 2005, September 17, 2005, and September 22, 2005. Respondent's office (Novella) was closed on August 20, 2005, August 23, 2005, August 25, 2011, September 6, 2005, September 10, 2005, September 13, 2005, September 15, 2005, September 17, 2005, and September 22, 2005.

42. Respondent submitted statements to Medicare claiming that on June 7, 2005, June 9, 2005, July 7, 2005, July 12, 2005, July 19, 2005,

August 20, 2011, August 23, 2005, August 25, 2005, September 6, 2005, September 15, 2005, September 17, 2005, and September 22, 2005, he prescribed 480 mcg of Filgrastim (G-CSF) as part of the patient's treatment for HIV. Medicare will consider G-CSF medically reasonable and necessary for severe chronic neutropenia (SCN) patients to reduce the incidence and duration of sequelae of neutropenia, e.g., fever, infections, ulcers in symptomatic patients with SCN. Medicare will also consider G-CSF medically reasonable and necessary for off-label indication of amelioration of leucopenia in AIDS patients on AZT or AIDS patients with chorioretinitis on Ganciclovir. For Medicare to consider whether G-CSF is medically reasonable and necessary, medical record documentation maintained by the physician must clearly indicate the patient's current ANC; the patient's weight in kilograms; the administration and dosage of G-CSF; the actual indication for which the drug was given and accompanying symptomology (e.g., a fever, infections, ulcers in symptomatic patients with SCN); and, the patient's response to the treatment. Respondent's medical record did not contain any progress notes, any documentation of the billed diagnosis of neutropenia alonge with the indication and the symptomology, any documentation of the response to the medication. The laboratory reports were dated June 14,

2005, after the June 7, 2005 and June 9, 2005, billing dates. Additional laboratory reports dated August 11, 2005, before the billing date of August 20, 2005, reflected that the patient's ANC count was 2,382, which is well within normal limits (1500-7800 cells/mcl). Respondent did not follow the recommended dosing and, or follow the recognized standard of care. Respondent's medical records do not document the procedure being performed; the records do not contain an accurate diagnosis necessitating the administration of G-CSF as prescribed; and the records do not support the procedure billed by Respondent.

43. Respondent submitted statements to Medicare claiming that on June 7, 2005, June 9, 2005, July 7, 2005, July 12, 2005, July 19, 2005, August 20, 2011, August 23, 2005, August 25, 2005, September 6, 2005, September 13, 2005, September 17, 2005, and September 22, 2005, he prescribed 200 units of Epoetin Alfa therapy as part of the patient's treatment for HIV. Medicare will consider Epoetin Alfa therapy medically reasonable and necessary for anemia of chronic renal failure, anemia induced by AZT, and anemia associated with the management of Hepatitis C. To initiate Epoetin Alfa therapy, the patient **must** have a documented anemia as evidenced by symptoms and hematocrit (HCT) < 33% or a hemoglobin (HGB) < 11g/d unless there is medical documentation

showing the need for Epoetin Alfa despite a HCT > 32.9 or a HGB > 11g/d. The physician **must** clearly document in the medical record that all requirements have been met and support the medical necessity for the use of Epoetin Alfa, including, but not limited to covered diagnoses, appropriate laboratory studies (including date and results of most recent HCT/HGB levels within last month), dosage, route of administration, frequency and duration of the treatment and the patient's response to the therapy. Respondent's medical record did not contain any progress notes, any documentation that the procedure was actually performed on the billed date of service, any documentation of a HGB < 11g/d or a HCT < 33% within the last month, any documentation of a covered diagnosis, and any documentation of the patient's response. Respondent's medical records do not contain any laboratory reports applicable to the billed dates of June 7, 2005 and June 9, 2005. Respondent did provide a complete blood count (CBC) laboratory report on June 16, 2005. The HGB count reflected on this lab report was within normal limits at 14.4 (normal values are 12.0 - 18.0 gm/dl) and the HCT was within normal limits at 42.9 (normal values are 37.0 – 52%). Respondent did not accurately diagnose and, or document the patient with anemia. Respondent did not document any medical necessity for the use of

Epoetin Alfa, including but not limited to covered diagnoses, appropriate laboratory studies, dosage, route of administration, frequency and duration of the treatment, and the patient's response to the therapy. Epoetin Alfa is supplied and billed per 1,000 units, according to Respondent's records he prescribed and, or administered 200,000 units for which he billed Medicare. Respondent did not follow the recommended dosing and, or follow the recognized standard of care.

44. On July 7, 2005, Respondent submitted duplicate claims (claim #1005195793190 and claim #1005202796240) to Medicare for 200 units (200,000 units) of Epoetin Alfa therapy as part of the patient's treatment for HIV.

45. Respondent submitted statements to Medicare claiming that on July 19, 2005, he administered 10mg of Voriconazole (Vfend) based upon Respondent's diagnosis of Candidal Esophagitis on June 11, 2005. Medicare will consider the administering of Vfend medically reasonable and necessary if the physician conducted clinical studies to substantiate the diagnoses of Candidal Esophagitis. Respondent's medical records do not include any clinical studies and, or the infusion note for July 19, 2005. Respondent's progress notes reflect that he ordered the medications in billable amounts not according to clinical dosages, since Vfend should be

ordered in mg. per kg. of weight in accordance with the manufacturer's specifications, and not in 1,500 IU as the Respondent's progress notes indicate. Respondent did not follow the recommended dosing and, or follow the recognized standard of care. Respondent's medical records do not document the procedure being performed; the records do not contain an accurate diagnosis necessitating the administration of Vfend as prescribed; and the records do not support the procedure billed by Respondent.

46. Respondent submitted statements to Medicare claiming that on August 20, 2005, August 23, 2005, August 25, 2005, and September 15, 2005, he administered 10mg of Immune Globulin by intravenous as part of the patient's treatment for HIV. Medicare will consider Immune Globulin, Intravenous (IGIV) medically reasonable and necessary for autoimmune neutropenia when there is a decrease in the number of neutrophillic leukocytes in the blood due to an autoimmune mechanism. The disease is usually benign and self-limiting, and does **not** require treatment with IGIV. Occasionally, however, it is marked by repeated infection, IVIG may be recommended for the treatment of an absolute neutrophil count of less than 800mm; with **recurrent** bacterial infections. Medical record documentation maintained by the treating physician **must**

clearly document the medical necessity to initiate intravenous immune globulin therapy and the continued need thereof. Respondent's medical record included a laboratory report dated August 11, 2005, before the billing date of August 20, 2005, and it reflected that the patient's ANC count was 2,382, which is well within normal limits (1500-7800 cells/mcl). The patient's white cell count was also within normal limits. Respondent's medical records did not include any progress notes and any documentation that the patient is prone to repeated episodes of infection. Respondent did not follow the recommended dosing and, or follow the recognized standard of care. Respondent's medical records do not document the procedure being performed; the records do not contain an accurate diagnosis necessitating the administration of IVIG as prescribed; and the records do not support the procedure billed by Respondent.

47. On August 20, 2005, Respondent submitted duplicate claims (claim #1005263223170 and claim #1105249134840) to Medicare he administered 10mg of Immune Globulin by intravenous as part of the patient's treatment for HIV.

48. Respondent submitted statements to Medicare claiming that on August 23, 2005, August 25, 2005, September 6, 2005, September 10, 2005, September 13, 2005, September 17, 2005, and September 22,

2005, he administered 50 mcg of Sargramostim (GM-CSF) as part of the patient's treatment for HIV. Medicare will consider medically reasonable and necessary for the treatment of primary neutropenia, AIDS, AIDS associated neutropenia caused by the disease AIDS itself or infection with opportunistic organisms (e.g., cytomegalovirus), or antiretroviral agents (Zidovudine or Ganciclovir). Medical record documentation maintained by the treating physician **must** clearly document the patient's current ANC; the patient's weight in kilograms; the administration and dosage of GM-CSF; the actual indication for which the drug was given and accompanying symptomology; and, the patient's response to the treatment. Respondent's medical record did not contain any progress notes, any documentation that the procedure was actually performed on the billed date of service, any actual indication of why the drug was given, any documentation of a covered diagnosis, and any documentation of the patient's response. Respondent's medical records do not contain any indication that the patient is having episodes of fever of more than 10 days duration or invasive pneumonia, cellulites, abscess, sinusitis, hypotension, multi-organ dysfunction, or invasive fungal infection. Respondent's medical record included a laboratory report dated August 11, 2005, and it reflected that the patient's ANC count was 2,382, which is

well within normal limits (1500-7800 cells/mcl). Respondent did not follow the recommended dosing and, or follow the recognized standard of care. The records do not contain an accurate diagnosis necessitating the administration of GM-CSF as prescribed by Respondent.

49. Respondent did not accurately and completely document the patient's condition and treatment, and he did not pursue an appropriate plan of treatment for the patient.

50. Respondent's medical records do not justify the course of treatment utilized in the care of the patient, and his medical records do not support or justify the fees and costs for procedures billed.

51. Respondent submitted statements to Medicare claiming that he provided medical services for the patient on August 20, 2005, August 23, 2005, August 25, 2011, September 6, 2005, September 10, 2005, September 13, 2005, September 15, 2005, September 17, 2005, and September 22, 2005, while Respondent's office was closed on those dates.

COUNT ONE

52. Petitioner re-alleges paragraphs 1 through 51 and incorporates them as if set out herein.

53. Section 458.331(1)(t), Florida Statutes (2004-2005), subjects a licensee to discipline for gross or repeated malpractice or the failure to practice medicine with that level of care, skill, and treatment which is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances.

54. On or between June 7, 2005, and September 25, 2005, Respondent failed to practice medicine within the standard of care in the treatment of Patient NB and, or Patient DA, in one or more of the following ways:

a. By failing to accurately diagnose the nature of the patients' condition before beginning treatment;

b. By failing to obtain appropriate laboratory studies to necessitate the prescribing and, or administering treatment;

c. By failing to obtain an accurate and correct diagnosis of the patients' medical condition necessitating the prescribing and, or administering Neupogen;

d. By failing to obtain an accurate ANC to necessitate the prescribing and, or administering of Neupogen;

e. By prescribing and, or administering Neupogen without medical necessity when laboratory studies reflected the ANC was within

normal limits;

f. By failing to obtain an accurate and correct diagnosis of the patients' medical condition necessitating the prescribing and, or administering Filgrastim;

g. By failing to obtain an accurate ANC to necessitate the prescribing and, or administering of Filgrastim;

h. By failing to obtain an accurate diagnosis of severe chronic neutropenia (SCN) to necessitate the prescribing and, or administering of Filgrastim;

i. By prescribing and, or administering Filgrastim without medical necessity when laboratory studies reflected the ANC was within normal limits;

j. By failing to obtain an accurate diagnosis of Type I Gaucher disease necessitating the prescribing and, or administering Imiglucerase;

k. By failing to obtain an accurate and correct diagnosis of the patients' medical condition necessitating the prescribing and, or administering of Voriconazole;

l. By failing to obtain an accurate and correct diagnosis of Candidal Esopagitis necessitating the prescribing and, or administering of Voriconazole;

m. By failing to prescribe and, or administer the appropriate recommended doses of Voriconazole;

n. By prescribing and, or administering Epoetin Alfa therapy without medical necessity when laboratory studies reflected that the patients' hematocrit (HCT) and hemoglobin (HGB) results were within normal limits;

o. By prescribing and, or administering Epoetin Alfa therapy without obtaining current laboratory studies of the patients' HCT and hemoglobin HGB levels;

p. By failing to obtain an accurate and correct diagnosis of an anemia of chronic renal failure, anemia induced by AZT, and, or anemia associated with the management of Hepatitis C, necessitating the prescribing and, or administering of Epoetin Alfa therapy;

q. By excessively prescribing and, or administering 200,000 units of Epoetin Alfa;

r. By failing to obtain an accurate and correct diagnosis of anemia (in Zidovudine-treated HIV-infected patients) necessitating the prescribing of Procrit;

s. By failing to prescribe and, or administer the appropriate recommended doses of Procrit;

t. By failing to obtain an accurate and correct diagnosis necessitating the prescribing and, or administering of Rituximab;

u. By failing to prescribe and, or administer the appropriate recommended doses of Rituximab;

v. By prescribing and, or administering Immune Globulin, Intravenous without medical necessity when laboratory studies reflected that the patient's ANC and white cell counts were within normal limits;

w. By failing to obtain an accurate and correct diagnosis of repeat autoimmune neutropenia necessitating the prescribing and, or administering of Immune Globulin, Intravenous;

x. By prescribing and, or administering Sargramostim without medical necessity when laboratory studies reflected that the patient's ANC and white cell counts were within normal limits, and there was no accompanying episodes of fever of more than 10 days, invasive pneumonia, cellulites, abscess, sinusitis, hypotension, multi-organ dysfunction, or invasive fungal infection;

y. By failing to obtain an accurate and correct diagnosis of primary neutropenia, AIDS associated neutropenia caused by the disease AIDS itself or infection with opportunistic organisms (e.g., cytomegalovirus), or antiretroviral agents (Zidovudine or Ganciclovir).

necessitating the prescribing and, or administering of Sargramostim;

z. By failing to obtain an accurate diagnosis of Type I Gaucher disease necessitating the prescribing and, or administering Imiglucerase;

aa. By failing to obtain an accurate diagnosis necessitating the prescribing and, or administering of intravenous infusion-hydration therapy;

bb. By failing to obtain an accurate diagnosis necessitating the prescribing and, or administering of intravenous infusion of saline solution;

cc. By failing to pursue an appropriate treatment plan for the patient(s);

dd. By failing to prescribe and, or administer antiretroviral medications as part of the patients' treatment for HIV;

ee. By failing to not consult with any specialists, or refer the patient to any specialists, for an accurate diagnoses and proper treatment of the patients' complaints and medical condition;

ff. By failing to consider or use any other treatment modalities for the patients' treatment for HIV.

55. Based on the foregoing, Respondent violated Section 458.331(1)(t), Florida Statutes, by engaging in gross or repeated

malpractice or by failing to practice medicine with that level of care, skill, and treatment which is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances.

COUNT TWO

56. Petitioner re-alleges paragraphs 1 through 51 and incorporates them as if set out herein.

57. Section 458.331(1)(k), Florida Statutes (2004-2005), sets forth grounds for disciplinary action by the Board of Medicine for making deceptive, untrue or fraudulent representations in or related to the practice of medicine or employing a trick or scheme in the practice of medicine.

58. Respondent participated in a scheme wherein false medical records were created for Patient NB and, or Patient DA, to support fraudulently billing to Medicare for unnecessary or unreasonable care and services.

59. Based on the foregoing, Respondent has violated Section 458.331(1)(h), Florida Statutes (2004-2005), for making deceptive, untrue or fraudulent representations in or related to the practice of medicine or employing a trick or scheme in the practice of medicine during his treatment of Patient NB and, or Patient DA.

COUNT THREE

60. Petitioner re-alleges paragraphs 1 through 51 and incorporates them as if set out herein.

61. Section 458.331(1)(h), Florida Statutes (2004-2005), provides that making or filing a report which the licensee knows to be false, intentionally or negligently failing to file a report or record required by the state or federal law, willfully impeding or obstructing such filing or inducing another person to do so constitutes grounds for discipline by the Board of Medicine. Such reports or records shall include only those which are signed in the capacity as a licensed physician.

62. Respondent knowingly, intentionally or negligently made or filed false insurance reports for office visits and, or therapy sessions that were never provided to Patient NB and, or Patient DA, or for care and services that were unnecessary or unreasonable.

63. Based on the foregoing, Respondent has violated Section 458.331(1)(h), Florida Statutes (2004-2005), by filing false reports.

COUNT FOUR

64. Petitioner re-alleges paragraphs 1 through 51 and incorporates them as if set out herein.

65. Section 458.331(1)(m), Florida Statutes (2004-2005), subjects a licensee to discipline for failing to keep legible, as defined by department rule in consultation with the board, medical records that justify the course of treatment of patients, including, but not limited to, patient histories, examination results, test results, or treatment plans.

66. Respondent failed to maintain medical records justifying the alleged treatment of Patient NB and, or Patient DA.

67. Respondent failed to maintain medical records justifying the fees and costs for the alleged treatment of Patient NB and, or Patient DA.

68. Based on the foregoing, Respondent has violated Section 458.331(1)(m), Florida Statutes (2004-2005), by failing to keep legible, as defined by department rule in consultation with the board, medical records that justify the course of treatment of patients, including, but not limited to, patient histories, examination results, test results, or treatment plans.

WHEREFORE, the Petitioner respectfully requests that the Board of Medicine enter an order imposing one or more of the following penalties: Permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of the Respondent on probation, corrective action, refund of

fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 24th day of June, 2011.

H. Frank Farmer, Jr., M.D., Ph.D.,
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DEPARTMENT OF HEALTH
DEPUTY CLERK
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DATE: 6/27/2011

MJS
PCP Members: El-Bahri, Espinola, Mullins
PCP Date: June 24, 2011

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or his behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.